

REMARKS

Applicant has revised the claims in accordance with the Advisory Action. Because of this and because withdrawal of the remaining obviousness rejections thereby is warranted (see below), applicant submits that entry of this supplemental response after final rejection is warranted.

Claim 1 is revised above to incorporate language adapted from claim 8, now cancelled, and supported in the specification, *e.g.*, at paragraph 0043 of the published application, US 2007/0092960. Accordingly, amended claim 1 qualifies the nature of the “fluid” from which bio-molecules are isolated.

Evidence of Criticality

In the penultimate paragraph of the Advisory Action (“Continuation Sheet”), Examiner Kim has stated that he finds “no evidence of record that” temperature “is critical” at which separation is carried out is, pursuant to the claimed invention. To the contrary, however, applicant would emphasize the common knowledge, *e.g.*, in the food-processing industry that processing and storage of food products should take place at as low a temperature as possible, in order that microbial growth and other decomposition processes are hindered.

See paragraph 0006 of the published application, which speaks in this regard of “a general need” in conventional technology “to keep processing temperatures below 10 – 15 degrees Celsius.” See also the accompanying chapter, entitled “Refrigerated Storage,” from a standard textbook in the field, PRINCIPLES OF FOOD PROCESSING by D. R. Heldman and R. W. Hartel (Chapman & Hall, 1997), ISBN: 0-8342-1269-2.

On page 83 of this excerpt, there is commentary in the last paragraph to the effect that the primary purpose of refrigerating foods is to extend shelf-life by slowing down degradatory reactions and limiting microbial growth. Typically, refrigerated storage means holding food in the temperature range of -1 to 8°C (*id.*, last sentence). Figure 5.1 of the excerpted chapter, at page 96, illustrates how higher processing and storage temperatures are associated with higher microorganism growth. Also, Table 5.6 on pages 99 and 100 sets out the minimum temperatures at which various spoilage bacteria require to be active, and most of these are below 0°C. This

temperature interval corresponds to the problem that applicant's claimed invention has solved by the present invention, as described in paragraph 0008 of the published application.

From this evidence, therefore, it is apparent that the art for decades has considered as critical the temperature at which food products are processed and stored. Thus, there is a clear understanding by those in the field that many food products should be processed and stored at temperatures below 10°C, so as to limit degradation and microbial growth.

Non-Obviousness Over the Art of Record

Applicant's previous response underscored how data reasonably gleaned from WO 02/096215 to Lihme *et al.* would have pointed the skilled artisan away from combining higher temperature with higher flow rates when processing food products according to the claimed invention. Example 9 of Lihme '215 shows a fall in the yield at increased loading, for instance, while Example 11 shows a rise and then a fall in the yield at increased temperature.

Thus, informed by Example 11, in column C (carried out at 50°C), the person of ordinary skill would have confronted the problem of countering decreasing yield with increasing temperature. There would have been a number of options available in this regard, such as changing the pH, changing the dimensions or nature of the column, and changing the nature of the flow liquid. Given the evidence in Example 9, however, raising the flow rate would not have been the obvious answer, since raised flow rate was associated with lower yield.

While acknowledging applicant's point, Examiner Kim has cited MPEP §2144.05, with its focus on criticality, vis-à-vis the prior art, with respect to "differences in concentration or temperature," in order to frame the examiner's conclusion that "it would have been obvious ... to increase flow rate *and* temperature to adapt the [conventional] purification process as necessary to obtain optimal market adaptation as taught by Lihme" (emphasis added). Yet, as explained above, only knowledge of applicant's claimed invention could have prompted the skilled artisan to select higher flow rate among other options, *contra* Lihme's Example 9, to combine with higher temperature, *contra* the common knowledge highlighted above.

Examiner Kim thus must be understood to have applied impermissible hindsight to substantiate the alleged *prima facie* case under Section 103. That such hindsight underpins his analysis is evident from a reading of MPEP §2144.05 itself, which states that:

... *A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation.*

It is clear, however, that higher flow rate is not a “result-effective variable” in the present context or, more to the point, could not have been recognized as such without the hindsight afforded by applicant’s own invention.

Regarding this point, applicant would direct the examiner’s attention to Lihme ‘215 at page 14, lines 14-28. In essence, this passage teaches that EBA processes may be run at very high flow rates but that the result might well be “poor and inefficient adsorption,” due to the fact that binding of the target molecules requires that they not diffuse in and out of the adsorbent particles to match this flow rate. The Lihme commentary goes on in the next paragraph to state that, as a consequence, “where the applied linear flow rate is above 300 cm/hr, the mean particle diameter is below 150 μm .” The remainder of the paragraph elaborates on this link of flow rate to particle diameter in the EBA column.

Thus, Lihme ‘215 teaches that raising the flow rate (a) is not straightforward and, in particular, (b) is linked to at least one other parameter, *i.e.*, particle diameter in the column. So informed, the skilled artisan could not reasonably have concluded that raising the flow rate would be brought off without technical difficulties or without considering other parameters.

By the same token, as Lihme ‘215 itself shows, there in fact would have been no recognition of flow rate in an EBA column as a “result-effective variable.” To the contrary, Lihme ‘215 discloses that the flow rate is linked to a number of parameters and that high flow rates actually can result in poor and inefficient adsorption in the EBA process. In other words, the evidence of record reveals not only that flow rate is the antithesis of result-effective, within the meaning of MPEP § 2144.05, but also that the skilled artisan would have been disincentivized from raising flow rate without consideration of other parameters, including temperature, and without expectation of technical difficulties.

The disclosures of Olander *et al.* do not mitigate what the skilled artisan would have understood from Lihme '215 regarding the difficulties and other considerations implicated by an increasing flow rate. Accordingly, no permutation of teachings reasonably drawn from Lihme '215 and Olander could have rendered the subject matter of claim 1 obvious, per Section 103.

The Commissioner is hereby authorized to charge any additional fees, which may be required under 37 C.F.R. §§ 1.16-1.17, and to credit any overpayment to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account. If any extension is needed for timely acceptance of submitted papers, then applicant hereby petitions for such extension under 37 C.F.R. § 1.136 and authorizes payment of the relevant fee(s) from the deposit account.

Respectfully submitted,

By 

Date September 13, 2010

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